DAPTACEL®

Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine DTaP

Manufacturer Sanofi Pasteur

Brand Name DAPTACEL®

Formulation 10 one-dose vials

Dosage 0.5ml

Storage Refrigerate immediately. Store at 2°-8° C (35°-46° F). **Do not freeze**.

Injection Site Anterolateral aspect of the upper thigh or deltoid

Route Intramuscular (IM)

Needle Size 22 to 25 gauge, 1 -1.5 inch

Administration May be administered simultaneously or at any interval between doses with

inactivated or live antigen.

Schedule for DAPTACEL vaccination of children:

Dose Customary AgeMinimum IntervalDose 1 2 months6 weeks or olderDose 2 4 months4 weeks after first doseDose 3 6 months4 weeks after second doseDose 4 15-18 months6 months after third dose*Dose 5 4-6 years6 months after the fourth dose

The fifth dose is not necessary if the fourth dose was administered on or after the 4th birthday. *The 4th dose of DTaP may be administered as early as 12 months of age, provided 6 months have elapsed since the 3rd dose, and if the child is considered unlikely to return at 15-18 months of age.

DTaP series should be completed with the same brand of vaccine if possible however there is limited data that suggests that DTaP interchangeability with other DTaP brands does not adversely affect the safety and immunogenicity of the vaccine.

Contraindications to DTaP vaccination:

- 1. Severe allergic reaction (anaphylactic) to a vaccine component in DAPTACEL® or following prior dose of vaccine.
- 2. Encephalopathy, not due to another cause, occurring within 7 days following DTP/DTaP vaccination.

Precautions to DTaP vaccination:

- 1. Moderate to severe illness, if vaccination is deferred vaccinate when condition improves
- 2. Temperature equal to or greater than 40.5° C (105° F) within 48 hours of previous DTP/DTaP vaccination not due to another identifiable cause.
- 3. Collapse or shock-like state (hypotonic-hyporesponsive episode) within 48 hours of previous DTP/DTaP vaccination.
- 4. Persistent, inconsolable crying lasting more than 3 hours, occurring within 48 hours of previous DTP/DTaP vaccination.

- 5. Convulsions with or without fever occurring within 3 days of previous DTP/DTaP vaccination.
- 6. Evolving neurologic disorder (e.g. uncontrolled epilepsy, infantile spasms, and progressive encephalopathy) a history of seizures that has not been evaluated, or a neurologic event that occurs between doses of pertussis vaccine

Reference: Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Atkinson W, Wolfe S, Hamborsky J, McIntyre L, eds. 11th ed. Washington DC: Public Health Foundation, 2009

http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/pert.pdf

U.S FDA Licenses DAPTACEL® Vaccine for the Fifth Consecutive Dose in the Pediatric DTaP Immunization Series/Sanofi Pasteur

Rev. 09/17/09